**UNITED STATES**
**NUCLEAR REGULATORY COMMISSION**
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

June 16, 2006

Mr. Jack Coffey
Senior Vice President
Quality and Regulatory
Nuclear Pharmacy Services
Cardinal Health
7000 Cardinal Place
Dublin, OH 43017

SUBJECT: NRC INSPECTION REPORT 030-36973/06-002(DNMS) (FORM 591M Part 1)

Dear Mr. Coffey:

This letter refers to the routine inspection conducted on April 26, 2006, at your Stamford, Connecticut, facility with in office review through May 11, 2006. The in office review included a review of your corrective actions regarding air in-leakage identified in your iodine-131 air sampling system. The inspection results were discussed with Paul Gotti, Radiation Safety Officer, during a final telephonic exit briefing conducted on May 31, 2006.

This inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, independent measurements, and observation of activities in progress. Within the scope of this inspection, no violations of NRC requirements were identified; therefore, no response to this letter or the enclosed NRC Form 591M is required.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Should you have any questions concerning this inspection or enclosed report, please contact Ken Lambert of my staff at (630) 829-9633.

Sincerely,

John R. Madera, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-36973
License No. 34-29200-01MD

Enclosure: Inspection Report 030-36973/06-002

cc w/encl: State of Connecticut

NRC FORM 591M PART 1
(10-2003)
10 CFR 2 201

U.S. NUCLEAR REGULATORY COMMISSION

# SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

| 1. LICENSEE/LOCATION INSPECTED: | 2. NRC/REGIONAL OFFICE |
|---|---|
| Cardinal Health<br>Nuclear Pharmacy Services<br>Dublin, Ohio 43017<br><br>REPORT Nos 2006002 | **U.S. Nuclear Regulatory Commission**<br>**Region I, 475 Allendale Road**<br>**King of Prussia, Pennsylvania 19406-1415** |

| 3. DOCKET NUMBER(S) | 4. LICENSE NUMBER(S) | 5. DATE(S) OF INSPECTION |
|---|---|---|
| 03036973 | 34-29200-01MD | 4/26/2006 & info. provided 5/11/06 |

**LICENSEE:**

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

[X] 1. Based on the inspection findings, no violations were identified.

[ ] 2. Previous violation(s) closed.

[ ] 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied.

[ ] Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(s):

[ ] 4. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.

## Licensee's Statement of Corrective Actions for Item 4, above.

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

| Title | Printed Name | Signature | Date |
|---|---|---|---|
| **LICENSEE'S REPRESENTATIVE** | | | |
| **NRC INSPECTOR** | **Thomas K. Thompson** | | **5/17/06** |

NRC FORM 591M PART 3
(10-2003) 10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

*Docket File Information*

# SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

| 1. LICENSEE | 2. NRC/REGIONAL OFFICE |
|---|---|
| **Cardinal Health**<br>**Nuclear Pharmacy Services**<br>**Dublin, Ohio 43017**<br><br>REPORT NOS 2006002 | **U.S. Nuclear Regulatory Commission**<br>**Region I, 475 Allendale Road**<br>**King of Prussia, Pennsylvania 19406-1415** |

| 3. DOCKET NUMBER(S) | 4. LICENSE NUMBER(S) | 5. DATE(S) OF INSPECTION |
|---|---|---|
| 03036973 | 34-29200-01MD | 4/26/2006 & info. 5/11/06 |

| 6. INSPECTION PROCEDURES USED | 7. INSPECTION FOCUS AREAS | 8. INSPECTOR |
|---|---|---|
| 87127 | 03.01-03.07 | Thomas K. Thompson |

## SUPPLEMENTAL INSPECTION INFORMATION

| 1. PROGRAM CODE(S) | 2. PRIORITY | 3. LICENSEE CONTACT | 4. TELEPHONE NUMBER |
|---|---|---|---|
| 2500 | 2 | Anthony Colangelo, Manager | 203 352-1990 |

| | | |
|---|---|---|
| | Main Office Inspection | Next Inspection Date: _____ |
| x | Field Office | 28 Omega Drive , Building #7 , Stamford, Connecticut |
| | Temporary Job Site | _____ |

**PROGRAM SCOPE**

The licensee prepares 4-500 doses per day consisting of mostly Tc-99m, about (4) I-131 capsules per day and distributes Xe-133 (about 8 vials per week distributed). They have three pharmacists, and 4 technologists. The facilities consist of three dose preparation stations, a separate I-131 preparation area, and a separate area for the storage of generators. The licensee has two large runs of product per day , one 1:00 to 4:00 a.m. and one 8:00 to 10:00 a.m.

During the inspection the I-131 air sampling system was tested for integrity of the connections on the sampling system. Air in leakage was identified with the air sampler taking hood effluent samples. The license identified that the air sampler cartridge threads were worn and has ordered replacements. The licensee's average calculated I-131 effluent concentration has been about 10% of the permitted concentration and the inspector determined that it was not likely the in leakage would have caused the licensee to under estimate the effluent concentration to the extent that they would have likely exceeded a regulatory limit.

The licensee's reported extremity doses and whole body doses are well within the regulatory limits and bioassay data indicates uptake of I-131 is not significant.